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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/072,320	
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	First Named Inventor	Russell Mumper	
	Art Unit	1618	
	Examiner Name	Retford O. Berko	
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Michael C. Barrett
Michael C. Barrett

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Mumper *et al.*

Serial No.: 10/072,320

Filed: February 7, 2002

For: pH-Sensitive Mucoadhesive Film-Forming
Gels and Wax-Film Composites Suitable for
Topical and Mucosal Delivery of Molecules

Group Art Unit: 1618

Examiner: Retford O. Berko

Atty. Dkt. No.: NANO:002USD1/MCB

REPLY BRIEF

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REPLY BRIEF

BOX AF

Commissioner of Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Applicants submit this Reply Brief to the Board of Patent Appeals and Interferences in response to the Examiner's Answer dated October 20, 2005. No fee is believed due. However, should any fee be required for any reason, the Commissioner is authorized to deduct from Fulbright & Jaworski Deposit Account No. 50-1212/NANO:002USD1/MCB. Please date stamp and return the attached postcard as evidence of receipt. Favorable consideration of the present application is respectfully requested.

I. STATUS OF CLAIMS

In the Examiner's Answer ("Answer"), the Examiner states that claim 58 has been canceled. *See Answer*, page 3, item 3. Applicants respectfully disagree. While Applicants attempted to cancel claim 58 in response to the Final Office Action dated November 17, 2004, that amendment was not entered. Specifically, the Advisory Actions dated February 8, 2005, and April 4, 2005, refused entry of all amendments, one of which was the cancellation of claim 58. Applicants are not aware of any other time that claim 58 was canceled, or attempted to be canceled, and it is therefore believed that claim 58 is still properly in this case and subject to this appeal.

II. REMARKS

A. The Answer is premised on an erroneous view of the issues on appeal.

The Answer states the issues for appeal as follows: "Whether applicant's invention, *a wax-film composite or bilayer film that can adhere to the skin for delivery of drug to a site* is different from the invention taught in the prior art" *See Answer*, pages 3-4, item 6 (emphasis added). The analysis throughout the Answer is dedicated to answering this specific question in the negative. *See Answer*, pages 4-12. However, this question mischaracterizes the Applicants' invention, so the Examiner's associated analysis within the Answer is based on an erroneous premise.

Applicants' invention is not simply any "wax-film composite or bilayer film that can adhere to the skin for delivery of drug to a site," nor does independent claim 33 purport to be so broad. Independent claim 33 recites: "A wax-film composite comprised of a pH-sensitive mucoadhesive layer and a water-insoluble wax layer." Under law and rules cited by Applicants previously, and especially in view of the Federal Circuit's recent proclamations in *Phillips v.*

AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005), independent claim 33 must be read in view of the specification. *Id.*, 415 F.3d at 1315. When an applicant has offered a definition for one or more terms within the specification, those definitions must govern and cannot be ignored. *Id.*, 415 F.3d at 1316; *see also* M.P.E.P. § 2111.01. Here, at least the following terms within claim 33 are subject to explicit definition within the specification:

Claim Term	Definition	Specification Cite
wax-film composite	a bi-layer, bonded film	page 18, 2nd full paragraph
pH-sensitive	a substance that is affected by changes in pH so that the substance changes conformation, charge, solubility, or combinations thereof	page 16, 2nd full paragraph
mucoadhesive	a substance that sticks to or adheres to the skin or mucosal surfaces by forces that are measurable and by any number of mechanisms such as, but not limited to the following: hydrogen-bonding, ionic interaction, hydrophobic interaction, van der Waals interaction, or combinations thereof	page 19, 1st full paragraph

These definitions are conspicuously absent from the Examiner's statement of the "issues" of this appeal, and these definitions are likewise absent from any analysis within the Answer. When one considers the explicit requirements of claim 33, it is clear that no *prima facie* case of obviousness can be established based on U.S. Patent No. 4,959,218 ("Eckenhoff") combined with U.S. Patent No. 5,700,478 ("Biegajski") (collectively, "cited art"), as outlined in the Appeal Brief.

B. The citations provided by the Answer mischaracterize the cited art and are not supportive of a *prima facie* case of obviousness.

The citations provided by the Answer do not establish a bi-layer, bonded film having (1) a pH-sensitive mucoadhesive layer and (2) a water-insoluble wax layer.

1. *pH-sensitive mucoadhesive layer.*

In an attempt to arrive at the claimed pH-sensitive mucoadhesive, the Examiner repeatedly cites passages within Eckenhoff concerning Carbopol or Carbomer. *See Answer* pages 4-5, page 7. The Examiner argues that it would be obvious to include these materials from Eckenhoff within layers of Biegajski. *See Answer*, page 7. The Answer mischaracterizes the nature of Eckenhoff because the Carbopol or Carbomer within Eckenhoff is used as a “driving member” within an implantable device, and the driving member is a separate compartment that physically swells to push a drug through an opening of the implant. *See Eckenhoff*, col. 11, lines 22-60, Figure 3, element 17. Nothing in Eckenhoff teaches or suggests use of Carbopol or Carbomer within a mucoadhesive layer. In fact, nothing in Eckenhoff can be characterized as a mucoadhesive layer since it is an implanted device, and nothing suggests removing Carbopol from the specific driving-member portion of the Eckenhoff implant for insertion into a particular layer of the disparate Biegajski device.

2. *water-insoluble wax layer.*

The Examiner points to mentions of a “wax” within Biegajski in an attempt to establish the requisite water-insoluble wax layer of claim 33. *See Answer*, pages 5, 8-9. Such citations represent mischaracterizations of the art because Biegajski repeatedly emphasizes that its layers are water-soluble, not water-insoluble; thus, Biegajski actually teaches away from Applicants’ claim 33. *See Biegajski*, col. 3, lines 35-41 (“The pressure-sensitive adhesives of the invention are fully water-soluble ...”), col. 4, lines 57-63 (noting embodiments in which “all the layers are water soluble”); col. 5, lines 11-15 (“Because the materials of the layers are water soluble ...”); and col. 9, lines 18-22. Within the Answer at page 9, the Examiner cites to Biegajski at column 4, lines 35-40 as support for the water-insoluble wax layer. Reading this passage,

however, reveals that Biegajski is discussing occluding layers “constructed of a water-soluble polymer” possibly containing wax as an “additive.” *See* Biegajski, col. 4, lines 35-40. Biegajski’s disclosure of a wax “additive” in a water-soluble layer acting as an occluding layer does not amount to a disclosure or even a suggestion of a non-soluble wax layer at least because a wax additive is not a layer, and a water-soluble layer cannot suggest a water-insoluble layer (in fact, it teaches away). The Examiner also points to col. 4, lines 35-39 as support for a water-insoluble wax layer. *See* Answer, page 9. This too, however, is a mischaracterization, for this passage corresponds to Biegajski’s claim 30 that explicitly recites wax as being a possible component of a “water soluble layer.”

The Examiner also repeatedly points to the disclosure of wax within the implantable device of Eckenhoff as a disclosure or suggestion of the water-insoluble wax layer of claim 33. *See, e.g.,* Answer, page 6. This assertion is also revealed as a mischaracterization upon reading the specific citations from Eckenhoff. The wax of Eckenhoff is not bonded to or associated with any mucoadhesive layer as required by claim 33 (a mucoadhesive layer is totally absent in Eckenhoff since it is a device designed specifically for implantation). Instead, the wax of Eckenhoff is used to separate a driving member from a lumen (essentially, a hollow container for holding a drug). *See* Eckenhoff col. 6, lines 20-29, Figure 3, element 20. Further, no evidence has been presented to suggest taking this wax from Eckenhoff’s implant and placing it in one or more layers of Biegajski to yield a water-insoluble layer.

3. *additional Answer citations.*

Remaining citations within the Answer are directed to similar themes that do not establish obviousness. Namely, the Examiner cites several additional passages concerning waxes in an attempt to establish a water-insoluble wax layer without noting that those citations

are directed to either (1) a physical barrier for a driving member of an implanted device, not associated with any mucoadhesive layer, or (2) a possible additive for a water-soluble layer. The Examiner also cites additional passages concerning pH-sensitivity in an attempt to establish a pH-sensitive mucoadhesive layer without noting that Eckenhoff has no such mucoadhesive layer at all and only uses Carbomer as a driving agent to push a drug out of an orifice.

However, nowhere in the Answer has the Examiner pointed to any disclosure, or provided evidence that would suggest, a bi-layer, bonded film having (1) a pH-sensitive mucoadhesive layer and (2) a water-insoluble wax layer in combination as required by claim 33. Citations to clearly disparate elements that, even when pieced together, do not amount to the claimed subject matter cannot constitute a proper case of obviousness. Accordingly, the current rejections are believed to be unsupported both technically and legally. Additional, similar arguments concerning patentability are contained in the Appeal Brief and will not be repeated (*e.g.*, there is no motivation to combine the disparate technologies of the cited art and there is no reasonable expectation of success).

III. CONCLUSION

Applicants respectfully submit that the present claims are in condition for allowance. It is therefore requested that the Board overturn the rejections. Please date stamp and return the enclosed postcard to evidence receipt of this document.

Respectfully submitted,



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